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STATE PROCUREMENT OFFICE
NOTICE OF AND REQUEST FOR EXEMPTION FROM CHAPTER 103D, HRS

STATE PROCUREMENT OFFICE
STATE OF HAWAII

1. TO: Chief Procurement Officer

2. FROM: Health/State Laboratories/Medical Microbiology
Department/Division/Agency

Pursuant to §103D-102(b)(4), HRS, and Chapter 3-120, HAR, the Department requests a procurement exemption to purchase the following:

3. Description of goods, services or construction:
Human Immunodeficiency Virus Test Kits
HIV EIA Test Kits & Western Blot Test Kits

4. Name of Vendor: Bio-Rad Laboratories, Inc. Address: 1000 Alfred Nobel Drive Hercules, CA 94547	5. Price: $175,000
6. Term of Contract: From: CPO Approval PT To: 12 Months	7. Prior Exemption Ref. No. 09-050-B

8. Explanation describing how procurement by competitive means is either not practicable or not advantageous to the State:
Procurement by competitive means is not practicable or advantageous to the State.
The State Laboratories Division (SLD) needs to use an HIV-1/2 test approved for testing blood for oral fluid specimens because the oral fluid test manufacturer stopped making the tests ("off-label" use). Only Bio-Rad Laboratories is seeking FDA approval for inclusion of oral fluid for use with its HIV-1/2 + O blood test, so it is the only product known to us with a chance of eventual federal approval for detecting HIV-1 and HIV-2 antibodies in oral fluid specimens.

The test kits to be purchased are USFDA approved for the screening of human serum, plasma, and cadaveric serum for antibodies to the Human Immunodeficiency Virus (HIV) Types 1 (Groups M and O) and/or 2 (See Attached Sheet)

9. Details of the process or procedures to be followed in selecting the vendor to ensure maximum fair and open competition as practicable:
We already use both products for different types of patient specimens so there already is a fair and open competition. These are the only 2 FDA approved EIA tests for HIV-1 and HIV-2 and the products serve as primary or contingency products for SLD.

Bio-Rad Laboratories manufactures and is the sole distributor of the Genetic Systems HIV-1/2 + O EIA test kits, Bio-Rad Laboratories is the only known manufacturer that has declared its intention to submit for USFDA approval their product for use to screen oral fluid specimens for HIV-1 and HIV-2 antibodies. Our laboratory has selected to validate this product for use with oral fluid specimens based on current available information. (See Attached Sheet)

10. A description of the agency's internal controls and approval requirements for the exempted procurement:
The approval process within the Communicable Disease Division (CDD) for purchases >$5,000 requires CDD Chief or designee approval. The STD Program Coordinator is responsible for administering/monitoring of the contract.

11. P.E. No. 10-044-K

REQUEST FOR EXEMPTION FROM CHAPTER 103D, HRS (Cont.)

12. A list of agency personnel, by position, who will be involved in the approval process and administration of the contract:

Name	Position	Involvement in Process	
Venie Lee	Acting, STD Program Coordinator	☒ Approval	☒ Administration
Kevin Nomura	STD/AIDS Branch PHAO	☒ Approval	☐ Administration
Peter Whiticar	STD/AIDS Branch Chief	☒ Approval	☐ Administration
Dr. Glenn Wasserman	Communicable Disease Div. Chief	☒ Approval	☐ Administration
		☐ Approval	☐ Administration
		☐ Approval	☐ Administration

13. Direct inquiries to:
Department: Health
Contact Name: Gail Y. Kunimoto
Phone Number: 453-6700
Fax Number: 453-6716

Agency shall ensure adherence to applicable administrative and statutory requirements

14. ***I certify that the information provided above is, to the best of my knowledge, true and correct.***

Department Head

DEC 14 2009
Date

Reserved for SPO Use Only

15. Date Notice Posted 12/16/09

The Chief Procurement Officer is in the process of reviewing this request for exemption from Chapter 103D, HRS. Submit written objections to this notice to issue an exemption from Chapter 103D, HRS, within seven calendar days or as otherwise allowed from the above posted date to: Chief Procurement Officer
State Procurement Office
P.O. Box 119
Honolulu, Hawaii 96810-0119

Chief Procurement Officer's comments:

Approval is based on the department's representation that Bio-Rad will be used as a contingency plan should Maxim products become unavailable and is the only other manufacturer that produces USFDA Western Blot Test Kits. HRS section 103D-310(c), and HAR section 3-122-112 shall apply.

16.
☒ **APPROVED** ☐ **DISAPPROVED** ☐ **NO ACTION REQUIRED**

Chief Procurement Officer

3/8/2010
Date

11. P.E. No. 10-044-K

8. Explanation describing how procurement by competitive means is either not practicable or advantageous to the State:

(HIV-1/HIV-2). These agents have been identified as the causative agents of Acquired Immunodeficiency Virus Syndrome (AIDS). This product, from Bio-Rad Laboratories, who acquired Sanofi Diagnostics Pasteur, is marketed by their Genetic Systems division, uses recombinant and synthetic peptide antigens. The use of this type of antigen is believed to yield sensitive results, without a large number of false positives.

This product is intended to be used to primarily screen oral fluid specimens by enzyme immunoassay in our laboratory. Discontinuation by bioMerieux, Inc., manufacturer of the only FDA approved oral fluid HIV-1 EIA screening test at the end of 2007 has forced public health laboratories including the Florida Bureau of Laboratories and the San Francisco Public Laboratory to validate testing oral fluid specimens using a serum-based EIA in order to maintain testing of oral fluid specimens, which has shown to yield better sensitivity and specificity for HIV antibodies than that of other alternative body fluids to serum.

Avioq, Inc. has just announced that they have received FDA approval for use of their HIV-1 EIA with serum and oral fluid specimens in October 2009, however, it is only approved to detect HIV-1 antibody and not HIV-2 antibody and their product cannot be used to screen blood donors.

There are currently two USFDA approved supplementary or confirmatory tests by western blot for use on HIV-1 serum screen test reactive specimens. The USFDA approved western blot kits are the Cambridge Biotech HIV-1 Western Blot Test Kit manufactured and distributed by Maxim Biomedical, Inc. and the Bio-Rad HIV-1 Western Blot Test Kit. Procurement by competitive means for the Bio-Rad HIV-1 Western Blot Test Kit is not practicable or advantageous to the State because our laboratory already performs the Cambridge Biotech HIV-1 Western Blot Test as the primary supplementary/confirmatory test kit for HIV-1 antibody screen reactive specimens.

We seek to have the Bio-Rad HIV-1 Western Blot test available for contingency use, as may be needed if the test of the only competitor, Cambridge Biotech HIV-1 Western Blot, becomes unavailable.

9. Details of process or procedures to be followed in selecting the vendor to ensure maximum fair and open competition as practicable:

   Full validation of this product has proved to be a huge undertaking for this laboratory in order to meet very stringent criteria requirements by federal law for validation of an off label product. Our laboratory is in the process of completing a full validation/comparison study using the Bio-Rad HIV-1/2 + O EIA Test Kit with oral fluid specimens and not the short term interim proposal by the Association of Public Health Laboratories approved by the Centers for Medicare and Medicaid Services (CMS).

   The only other USFDA licensed product to screen for HIV-1/2 antibodies in serum by enzyme immunoassay is manufactured by Abbott Laboratories which our laboratory is currently performing. Our laboratory secured a sole source approval for the Abbott Laboratories HIV-1/2 EIA Test for use with serum specimens based on over 10 years of comparative laboratory data. In addition, our laboratory has over 13 years of documented data on the performance of this HIV-1/2 EIA assay. The current equipment and instrumentation is proprietary to Abbott Laboratories and is not compatible with any other manufacturer's reagent test kits.